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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,860	06/25/2001	David B. Weiner	UPN-3983	1975

7590

03/11/2003

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 03/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/888,860	WEINER ET AL.	
Examiner	Art Unit	
Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 13 and 17 is/are rejected.
- 7) ☒ Claim(s) 5, 9-12 and 14-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to an amendment filed 12/16/02. Claims 1-17 are pending in this application.

Response to Amendment

The formal drawings that applicant filed under separate cover have not been received.

Rejection of claim 8 under 35 U.S.C. 112, second paragraph, has been withdrawn in light of claim amendment.

The rejection of claims 1, 2, 5, 7, 9, 10, 12, 13, and 14 under 35 U.S.C. 102(b) over Matthey et al., (1999) is withdrawn upon reconsideration. The vector, pBMO.5, does contain a poly(A) site at the 3' end of the kanamycin gene that would block further expression of downstream genes and thus lacks the ability to express the ETA' gene.

The rejection of claims 11 and 16 under 35 U.S.C. 103(a) over Invitrogen in view of Bukrinsky et al. (Science 220 (4596) pp 515-519) is withdrawn upon reconsideration due applicant's arguments. While it is not conceded that one could not make an antisense molecule in pBK-CMV or P2Bac, there is no motivation to combine the teachings of Invitrogen (or Stratagene) with Bukrinsky et al.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene, 1992 catalog.

The Stratagene catalog describes a vector (pBK-CMV) comprising an SV40, F1 and ColE1 origin of replication, a CMV immediate early promoter and in the opposite orientation a T7 promoter, a multiple cloning site (polylinker), a SV40 poly adenylation site, neomycin (kanamycin) and G418 selectable markers (page 18-19). This vector can be used in bacteria to amplify a toxic gene under control of the CMV promoter. The T7 promoter is **capable** of producing an antisense molecule directed to said toxic gene. Rejections based upon pPbac have been withdrawn upon reconsideration, as this vector does not appear capable of producing an antisense molecule. **This rejection is maintained for reasons of record in Paper No. 5, mailed 12/16/02. This rejection is hereby extended to newly added claims 17.**

Claims 1, 2, 3, 4, 7 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Invitrogen, 1994 catalog.

The Invitrogen catalog describes a vector (p2Bac) comprising a ColE1 origin of replication, an enhancer-promoter sequence of AcMNPV polyhedrin Ppol in the opposite orientation of a p10 promoter, Pp10, that is **capable** of producing an antisense molecule directed to said toxic gene multiple cloning sites (polylinker), poly adenylation sites and ampicillin (page

41). Also provided is custom cloning and expression by Invitrogen (page 66). Rejection of claims 6 and 15 has been withdrawn upon reconsideration. **This rejection is maintained for reasons of record in Paper No. 5, mailed 12/16/02.**

Response to Arguments

On page 2-3 of the amendment filed 12/16/02, applicant traverses the rejection under 35 U.S.C 102(b) as anticipated by Stratagene. Applicant argues that the claimed invention is novel, as the vector pBK-CMV does not meet all of the limitations of the instant invention as the T7 promoter is used in vitro. Applicant argues that there is no promoter in the opposite orientation of the promoters used to express the toxic genes. Additionally, applicant states that an enhancer element is missing from pBK-CMV.

Applicant's arguments filed 12/16/02 have been fully considered but they are not persuasive. Submitted for clarification is a detailed map of pBK-CMV, which shows that a T7 promoter is in opposite orientation of the CMV and lac promoters. While this promoter is used in vitro for transcription this does not exclude its use in producing antisense molecules as the claim does not limit the production of the antisense molecules to in vivo conditions. Furthermore, the CMV immediate early promoter inherently contains both promoter and regulatory (enhancer) sequences as evidenced in Stinski et al, column 6, line 27-column 7, line 16.

On page 3-4 of the amendment filed 12/16/02, applicant traverse the rejection under 35 U.S.C 102(b) as anticipated by Invitrogen. Applicant argues that the claimed invention is novel, as the p2Bac vector does not encode a promoter in the opposite orientation of the promoters used

to express the toxic genes. Rather, the promoters are arranged to permit the simultaneous expression of two recombinant proteins from the same construct.

Applicant's arguments filed 12/16/02 have been fully considered but they are not persuasive. That the promoters of p2Bac can express two proteins simultaneously does not preclude the use of this vector for the expression of a toxic protein cloned 5' to the first promoter and for the production of an antisense molecule cloned 5' to the second promoter. The antisense molecule would necessarily lack a translation codon.

Claims 1-4, 6-8, 13 and 17 are rejected.

Claims 5, 9-12, 14-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucell, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1636

March 10, 2003

DAVID GUZO
PRIMARY EXAMINER
David Guzo